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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,744

06/20/2006

Tohru Yokozawa

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

PIHONAK, SARAH

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

09/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,744	Applicant(s) YOKOZAWA ET AL.	
	Examiner SARAH PIHONAK	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009 and 07 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/JP04/17998, filed on 11/26/2004.

Priority

This application, filed 6/20/2006, claims foreign priority to Application No. 2003-398201, filed on 11/27/2003.

Response to Arguments

1. In the office action dated 2/24/2009, claims 1-18 were rejected under 35 USC § 112, first paragraph, for lack of enablement. In the response filed on 6/23/2009, the Applicants cancelled claims 1-9 and 18, and amended claims 10-17. The rejection of claims 1-9 and 18 is considered moot due to their cancellation. In view of the amendments to claims 10-17, the rejection of these claims under 35 USC § 112, first paragraph is withdrawn.

In the office action dated 2/24/2009, claims 1-18 were rejected under 35 USC § 103(a) as being unpatentable over Andersson et. al., US 7,002,037 patent, in view of Burk et. al., JACS, **120**, pp. 4345-4353. The rejection of claims 1-9 and 18 is considered moot due to their cancellation. In the response filed on 6/23/2009, the Applicants have argued that it would not have been prima facie obvious for one of ordinary skill in the art to modify the teachings of the US '037 patent in view of the teachings from JACS '98 to arrive at the instant invention. The Applicants have argued that JACS '98 teaches

Art Unit: 1617

asymmetric hydrogenation of α , β -unsaturated carboxylic acids having an α O-acyl group, with a chiral rhodium metal catalyst, which is different from the instantly claimed compounds, as these compounds lack an α O-acyl group. The Applicants also cited two documents, *J. Org. Chem.*, 1980, **45**, pp. 2362-2365, and *JACS*, 1980, **102**, pp. 838-840, which teach asymmetric hydrogenation of compounds in which the α O-acyl group coordinates to the metal catalyst, facilitating the reaction. The Applicants have argued that since these documents teach asymmetric hydrogenation of compounds with an O-acyl group present, the instant invention is not obvious, as the instantly claimed compounds do not have an α O-acyl group. While this argument has been fully considered, it is not found to be persuasive. The US '037 patent teaches asymmetric hydrogenation of cinnamic acid derivatives which, as with the instantly claimed compounds, have an α -alkoxy group present. The US '037 patent teaches that the asymmetric hydrogenation can be performed with chiral catalysts, but does not explicitly teach specific types of chiral catalysts. The JACS '98 reference teaches asymmetric hydrogenation of α , β -unsaturated carboxylic acid compounds with chiral transition metal catalysts, such as rhodium. Therefore, as the US '037 patent teaches that asymmetric hydrogenation of cinnamic acid derivatives such as those instantly claimed can be performed with chiral catalysts, and JACS '98 teaches that chiral catalysts such as rhodium complexes are known to be used for asymmetric hydrogenation reactions, the instant claims would have been prima facie obvious to one of ordinary skill in the art. Though the JACS '98 reference does teach asymmetric hydrogenation of compounds which have an α O-acyl group, in which the instantly claimed compounds do not, this

Art Unit: 1617

reference was not relied particularly upon for this teaching. The US '037 patent already teaches that cinnamic acid derivatives, such as those instantly claimed, can successfully undergo asymmetric hydrogenation with chiral catalysts; the JACS '98 reference was utilized for teaching that transition metal chiral complexes such as rhodium complexes are effective for catalyzing asymmetric hydrogenation reactions. Therefore, one of ordinary skill in the art would have been motivated to use chiral transition metal catalysts such as rhodium complexes for facilitating asymmetric hydrogenation of the instantly claimed cinnamic acid derivatives, because the US '037 patent teaches that these compounds can undergo asymmetric hydrogenation with chiral catalysts, and JACS '98 teaches that rhodium complexes are used for asymmetric hydrogenation reactions. As such, one of ordinary skill in the art would have had an expectation of success in employing such a catalyst in the instantly claimed process. While the rejection of claims 1-18 under 35 USC § 103(a) over US '037 patent, in view of JACS '98 was proper, a modified rejection of the claims has been applied, due to the Applicants amendments to the claims. In addition the amendments to claims 10-17, new claims 19-22 have been added. The new claims find support from the specification and do not constitute new matter. The modified rejection of the claims under 35 USC § 103(a) will be discussed in detail further in this office action. Accordingly, this action is made **FINAL**.

2. Claims 10-17 and 19-22 were examined.
3. Claims 10-17 and 19-22 are rejected.

Art Unit: 1617

Claim Rejections-35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

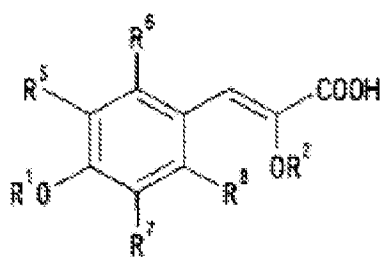
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 10-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et. al., US 6,258,850 patent, in view of Nohira, EP 408338

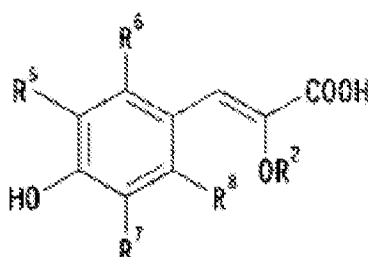
Art Unit: 1617

patent. The reference of Nohira ,EP 408338, was presented on the Information Disclosure Statement.

8. The instant claims are directed to a process for producing optically active phenyl propionic acids through asymmetric hydrogenation of the compounds of formula (4) and formula (9) as shown below:

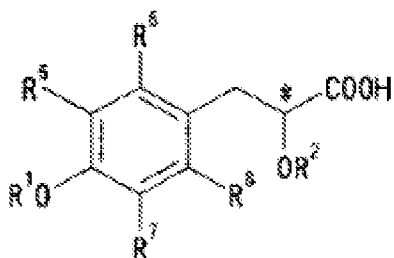


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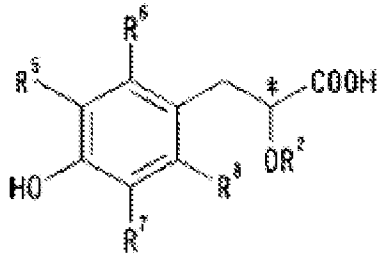


(9)

Where R^1 =protecting group; R^2 =alkyl group; R^5 - R^8 =H. The instant claims are also drawn to carrying out the hydrogenation in the presence of a chiral ruthenium complex, and that the resulting hydrogenated products, which are shown as compounds of formula (5) and (6) below, are further recrystallized after synthesis with solvents selected from hydrocarbons, alcohols, ketones, water, or mixtures thereof.



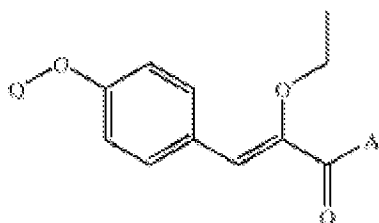
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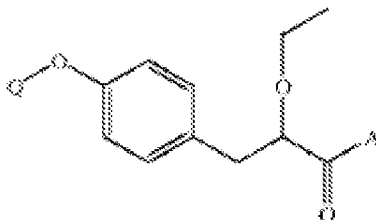
(6)

Art Unit: 1617

Andersson et. al. teaches that compounds of formula (VII) below can successfully undergo asymmetric hydrogenation to form compounds of formula (V), which is also shown below:



(VII)



(V)

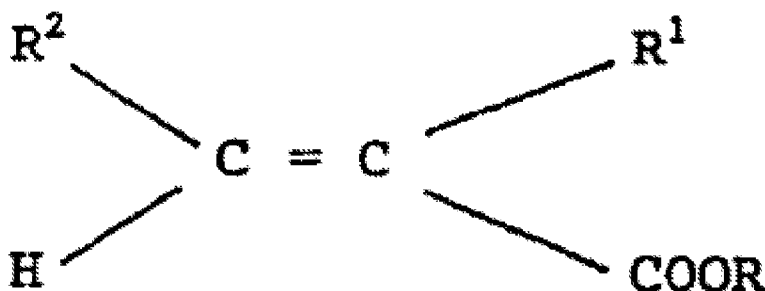
Where A=OH; Q=H or a protecting group (column 4, lines 29-46; column 7, line 50-column 8, line 24). The compounds taught by Andersson et. al. includes the compounds instantly claimed. Andersson et. al. teaches that the asymmetric hydrogenation reaction is conducted in the presence of chiral transition metal catalysts such as Rh-BINAP, [Et-DuPHOS-Rh(COD)], as well as a variety of other catalysts (column 8, lines 17-24). Crystallization of the products with solvents such as ethanol, isopropanol, and hydrocarbons and mixtures of solvents is taught (column 4, lines 66-67; column 13, lines 34-37; column 14, lines 42-45; column 15, lines 41-44). Andersson et. al. also teaches that the asymmetric hydrogenation can be performed in a wide variety of solvents (column 8, lines 25-32), and that protecting groups can be removed (column 5, lines 35-57).

While Andersson et. al. teaches that asymmetric hydrogenation can be successfully performed on compounds such as those instantly claimed, with chiral

Art Unit: 1617

rhodium complexes and other metal catalysts, chiral ruthenium complexes are not explicitly taught.

Nohira teaches that rhodium and ruthenium chiral complexes are effectively used for asymmetric hydrogenation of different compounds, such as α,β -unsaturated carboxylic acids (Abstract; p. 3, lines 23-47; p. 5, lines 10-13). Particularly, Nohira teaches that ruthenium and rhodium complexes with the 2,2'-bis(dicyclohexylphosphino)-6,6'-dimethyl-1,1'-biphenyl (BICHEP) ligand are effective catalysts for the asymmetric hydrogenation of α,β -unsaturated carboxylic acids, such as those compounds of formula (II) below (p. 3, lines 23-47; p. 3, line 48-p. 4, line 24; p. 5, lines 10-13):



Where R^2 =phenyl group, etc.; R^1 =lower alkyl group; R =H, etc. Nohira teaches that Rh or Ru (BICHEP) chiral complexes catalyze asymmetric hydrogenation reactions to give products of high optical purity and yield (p. 14, lines 1-8).

Andersson et. al. teaches that asymmetric hydrogenation can be successfully performed on compounds such as those instantly claimed in the presence of chiral catalysts, such as rhodium complexes. Nohira teaches that rhodium and ruthenium chiral complexes, such as Rh and Ru (BICHEP) complexes, are able to catalyze

Art Unit: 1617

asymmetric hydrogenation reactions to provide products of high optical purity and yield. It would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to carry out the asymmetric hydrogenation process of compounds taught by Andersson et. al. with Ru(BICHEP) chiral catalysts, because Andersson et. al. teaches that compounds such as those instantly claimed can successfully undergo asymmetric hydrogenation with chiral catalysts such as Rh-BINAP, [Et-DuPHOS-Rh(COD)], and Nohira teaches that Rh and Ru chiral complexes are both effective for asymmetric hydrogenation reactions. Therefore, as it is taught that Rh and Ru chiral complexes are both able to produce products of high optical purity and yield from asymmetric hydrogenation reactions, one of ordinary skill in the art would have expected success in substituting the chiral Ru(BICHEP) complex taught by Nohira for the chiral catalysts taught by Andersson et. al. such as Rh-BINAP, [Et-DuPHOS-Rh(COD)]. As these different types of catalysts are taught as being effective for asymmetric hydrogenation, it would have been obvious to use these catalysts for asymmetric hydrogenation reactions on the substrates taught by Andersson et. al., due to their equivalence in performing this reaction.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1617

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617